MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

August 12, 2008

MEMORANDUM

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: JOHN A. LIVERATTI, CHIEF OF COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATIONS

Changes to this chapter are the result of the recommendations of the Drug Use Review (DUR) Board meeting on January 24, 2008. Pursuant to NRS 422.403, the DUR Board manages step therapy and prior authorizations for prescription drugs. The DUR Board consists of six members (physicians and pharmacists) and is appointed by the Director of the Department of Health and Human Services.

The DUR Board specifically discussed and took action to update the clinical prior authorization criteria for drugs used to treat Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder in adults and children. The criteria was changed to allow for approval of these medications without a prior authorization under certain criteria. The clinical prior authorization criteria for growth hormone added IGF-1 testing. The clinical prior authorization criteria for hematopoietic agents (Epogen® and Procrit®, erythropoietin and Aranesp® darbepoetin) revises criteria.

| MATERIAL TRANSMITTED | MATERIAL SUPERSEDED |
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| **MTL20/08** | **MTL 21/03; 25/07; 02/07; 21/03** |
| CHAPTER 1200 – PRESCRIBED DRUGS | CHAPTER 1200 – PRESCRIBED DRUGS |
| Sec. 1200<br>Added "Nevada Check Up Manual Chapter 1000" | Deleted "Chapter 3700" |
| Sec. 1201<br>Added "8. Section 1927 of the Social Security Act requires the establishment of a Drug Use Review (DUR) board to monitor therapeutic appropriateness, use of generic products, overutilization and underutilization of drugs and quality of care consistent with protecting the health of | |

program beneficiaries."

Sec. 1203.1B.2.d.4

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| Added "that Medicaid will only pay for controlled substance" | Deleted "the" |
| Added "controlled substance prescriptions" | Deleted "recipient can only obtain payment" |
| Added "pharmacy" | Deleted "of the recipients choice." |
| | Deleted "/provider" |
| | Deleted "the service" |
| | Deleted "provider" |
| | Deleted "at another facility" |

Sec. 1205.1
Added "Medicaid Service Manuals:"
Added "Nevada Check Up Manual: Chapter 1000 Nevada Check Up Program"

Deleted "Chapter 3700 Nevada Check Up"

Sec. 1205.2.1.a

Deleted "Nevada"

Sec. 1205.2.1.b

Deleted "Belrose"

Appendix A.1.C
Added "Attention Deficit Disorder (ADD)/"

Added "ADD/"

Appendix A.1.C.1
Added "criteria is"

Deleted "are"

Appendix A.1.C.1.a.1
Added "long-acting"

Added "ADD/" twice in sentence

Added "be"

Appendix A.1.C.2
Added " 's"

Deleted "in order for Prior Approval of CNS Stimulants:"

Appendix A.1.C.2.a
Added "T"

Deleted "In the pediatric and adult

Added "must be"

population, t"

Deleted "and any comorbidty";

Deleted "at"

Appendix A.1.C.1.b
Added "conditions apply and"

Deleted "present and"

Added "1. Prescriptions for ADD/ADHD medications do not require prior authorizations for children five years of age, up to eighteen years of age, if the following conditions apply:

a. The medication is prescribed by a psychiatrist, and
b. One of the following ICD-9 codes is documented on the prescription: 314.0-314.9.

2. In all other cases, prior authorization is required. The following is required for prior authorization:"

Deleted "for Prior Approval of CNS Stimulants:"

Appendix A.1.C.1.b.2.a
Added "or examination"

Deleted "primary"

Added "within the past twelve months,"

Deleted "(e.g. fetal alcohol syndrome, thyroid disease) and examination within the past twelve months, or more recently, if the clinical condition has changed"

Added "a primary"

Added "of all of the following:"

Appendix A.1.C.1.b.2.a.1
Added bullet point "a"

Deleted "1."

Added "and"

Deleted "2. One of the following:"

Appendix A.1.C.1.b.2.a.2
Added bullet point "2."

Deleted "DMS-IV"

Added "DSM-IV"

Deleted "or"

Added "and"

Appendix A.1.C.1.b.2.a.3
Added bullet point "3."

Deleted "c."

Added "or guardian(s)."
Appendix A.1.C.1.b.3.

Deleted "3. The following two criteria must be met and documented in the recipient's

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| | medical record for adult and pediatric recipients in order for Prior approval of CNS Stimulants: a. In the pediatric and adult population, the decision to medicate for Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) and any comorbidty based on problems that are persistent and sufficiently severe to cause functional impairment in one or more of the following social environments: at school, home, work or with peers, and<br>b. Before treatment with pharmacological methods is instituted, other treatable causes have been ruled out." |
| Appendix A.1.C.1.c | |
| | Deleted "for Prior Approval of CNS Stimulants" |
| Appendix A.1.C.1.c.2.a<br>Added "primary" | Deleted "(e.g. thyroid disease head trauma)" |
| Added "identify" | Deleted "P" |
| Added "(s)" | |
| Added "p" | |
| Appendix A.1.C.1.c.2.b<br>Added "s" | |
| Appendix A.1.C.1.c.2.c<br>Added "T" | Deleted "t" |
| Appendix A.1.C.1.c.2.d | |
| | Deleted "PA forms" |
| Appendix A.1.D<br>Added "(GH)" | Deleted "All criteria must be met for children under 21 years of age. Adult cases will be reviewed on an individual basis." |
| Added "An FDA-approved indication for the diagnosis being treated is required." | |
| Appendix A.1.D.1.a<br>Added "The following apply to all requests for children:" | Deleted "The following criteria must be met for children under 21 years of age: Deleted "Indications for growth hormone therapy in children are growth hormone deficiency, growth retardation secondary to chronic renal insufficiency up until renal |

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| | transplantation and short stature of Turner's or Prader Willi syndrome" |
| Appendix A.1.D.1.a.1<br>Added "An evaluation by a pediatric endocrinologist or pediatric nephrologist with a recommendation for therapy." | Deleted "All other causes for short stature are ruled out" |
| Appendix A.1.D.1.a.2<br>Added "All other causes for short stature are ruled out." | Deleted "Bone Age Study results show less than sixteen years for boys, less than 14 years for girls; epiphysis open. Bone age is at least two years less than chronological age." |
| Appendix A.1.D.1.a.3<br>Added "Patient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonatropic hormones."<br><br>Added "Therapy will be approved for any one of the following:" | Deleted "Growth chart and declining growth velocity show growth less than fifth percentile. At least three documented measurements over the last six month period." |
| Appendix A.1.D.1.a.4<br>Added "Diagnosis of Turner's Syndrome. | Deleted "Evaluation by a Pediatric Endocrinologist or Pediatric Nephrologist with a recommendation for therapy." |
| Appendix A.1.D.1.a.5<br>Added "Diagnosis of Prader-Willi Syndrome." | Deleted "At lest two provocative stimuli tests to show failure to raise growth hormone level above 10nb (nanograms)/ml. Exception: Patients with Chronic Renal Insufficiency (CRI)." |
| Appendix A.1.D.1.a.6<br>Added "Patient has chronic renal insufficiency (defined as Creatinine Clearance between 5 and 75/ml/min/1.73m2)." | Deleted "Baseline blood tests abnormalities to be corrected." |
| Appendix A.1.D.1.a.7<br>Added "If the patient has evidence of hypothalamic-pituitary disease or structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation and meeting any one of the following: Patient has not undergone renal transplant.<br>a. Has failed at least one GH stimulation test (peak GH level <10 nanograms | Deleted "Turner's and Prader Willi syndrome documented by karotyping." |

(ng/ml).

b. At least one documented low IGF-1 level (below normal range for patients age – refer to range on submitted lab document).
c. Has deficiencies in three or more pituitary axes (i.e. TSH, LH, FSH, ACTH, ADH)."

Appendix A.1.D.1.a.8

Added "If the patient is a newborn infant and has evidence of hypoglycemia and either a low GH level (<20ng/ml) or a low for age IGF-1 or IGF Binding Protein #3 level (IGFPB#3) (no stimulation test required for infants)."

Deleted "No expanding intracranial lesion or tumor diagnosis."

Appendix A.1.D.1.a.9

Added "Children with a history of intrauterine growth restriction (small for gestational age (SGA)) who at age two years have a height at least two Standard Deviations (SD) below the mean for the patient's age and gender."

Deleted "MRI or CT scan of head done on patients with multiple pituitary hormone deficiencies or history of intracranial lesions."

Appendix A.1.D.1.a.10

Added " For Idiopathic Short Stature all of the following criteria must be met:

a. Bone age>2 SD below the mean for age, Epiphysis open.
b. Height >2.25 SD below the mean for age or >2 SD below the mid-parenteral height percentile or growth velocity <25$^{th}$ percentile for bone age.
c. At least one provocative stimuli test to show failure to raise the growth hormone level about 10ng/ml.
d. Exception to the requirement for stimuli testing: Patients meeting (10)(a) and (10)(b) above in addition to a documented low serum insulin-like growth factor 1 (IGF-1) and/or insulin-like growth factor binding protein #3 (IGFPB#3) will not be required to have stimuli testing.

Appendix A (1)(D)(1)(b)

Added "the"

Added "for children"

Added "all of"

Appendix A.1.D.1.b.1
Added "Bone age >2 below the mean for age. Epiphysis open."

Deleted "Bone age study shows less than sixteen years for boys, less than fourteen years for girls. Epiphysis open."

Appendix A.1.D.1.b.2
Added "centimeters"

Deleted "cm"

Added "the"

Appendix A.1.D.1.b.3

Deleted "adult"

Appendix A.1.D.1.c

Deleted "Covered ICD-9 codes:
Panhypotituitarism
Pituitary Dwarfism
Latrogenic pituitary disorders
Other disorders of the pituitary and other syndromes of diencepalohypophyseal origin
Other disorders of the pituitary gland and craniophryngeal duct
Chronic renal failure
Unspecified disorder resulting from impaired renal function
Gonadal dysgenesis/Turner's syndrome
759.81 Prader Willi syndrome

Appendix A.1.D.1.c.6

Deleted "adult"

Appendix A.1.D.1.d
Added "Indications for growth hormone therapy in adults are: Adults who were growth hormone deficient as children or adolescents. All of the following criteria must be met:"

Deleted "The following criteria must be met for adults 21 years of age and older."

Deleted "e.) Agents selected for treatment must have an FDA approved indication for the diagnosis being treated as stated in the package insert."

Appendix A.1.D.1.d.1-4
Revised and added new criteria

Appendix A.1.D.1.e.2.
Added "a. Patient has failed to adequately respond to dietary measures.
b. Patient has failed to respond or is intolerant to appetite-stimulating drugs, (e.g. Megace) and anabolic steroids.

c. Absence of a concurrent illness or medical condition other than HIV infection that would explain these findings."

Added "Prior Authorization will be given for 12 weeks."

Added "the Prior Authorization"

Added "Prior Authorization"

Appendix A.2

Deleted "PA Guidelines"

Appendix A.1.G
Added "This policy applies in all settings with the exception of inpatient facilities."

Added "also known as erythropoiesis stimulating agents (ESAs)

Added "one of"

Added "following"

Appendix A.1.G.1.a.1
Added specific criteria to "Coverage and Limitations"

Deleted "Approval will be given for the sue of Red Blood Cell Building Hematopoietics and Hemantinics if a diagnosis of anemia and the cause (e.g. chronic renal failure, myclosuppressive chemotherapy) is documented and confirmed by blood test."

**Appendix A (1)(G)(2)(a, b, c, d, e, f, g, h)**
Added title and definition of "Non-covered Indications:"

Added "Claims documenting doses exceeding the Center for Medicare and Medicaid Services (CMS's) maximum threshold for ESAs will be denied."

Added "Recent laboratory results are required for Prior Authorization, i.e., serum hemoglobin within seven days of Prior Authorization request."